DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-698

Braintree Laboratories, Inc.
Attention: Mark vB. Cleveland, Ph.D.
60 Columbian Street
P.O. Box 850929
Braintree, MA 02185

FEB 18 1999

Dear Dr. Cleveland:

Please refer to your new drug application (NDA) dated February 26, 1996, received February 28, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for MiraLax (polyethylene glycol 3350, NF) Powder.

We acknowledge receipt of your submissions dated December 7, December 14, December 17, 1998, February 8, and February 11, 1999.

This new drug application provides for the use of MiraLax (polyethylene glycol 3350, NF) Powder for occasional constipation.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert, patient package insert, and immediate container labels submitted February 11, 1999). Accordingly, the application is approved effective on the date of this letter.

At the next printing of the labeling, please revise the patient information sheet and the package insert so that they can be separated and the patient information sheet given to the patient.

We remind you of your Phase 4 commitments specified in your submission dated December 17, 1998.

Protocols, data, and final reports should be submitted to your IND for this product and a copy of the cover letter sent to this NDA. If an IND is not required to meet your Phase 4 commitments, please submit protocols, data and final reports to this NDA as correspondence. In addition, under 21 CFR 314.82(b)(2)(vii), we request that you include a status summary of each commitment in your annual report to this NDA. The status summary should include the number of patients entered in each study, expected completion and submission dates, and any changes in plans since the last annual report. For administrative purposes, all submissions, including labeling supplements, relating to these Phase 4 commitments must be clearly designated "Phase 4 Commitments."

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact Alice Kacuba, Consumer Safety Officer, at (301) 827-7310.

Sincerely,

Lilia Talarico, M.D.
Director
Division of Gastrointestinal
and Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research